QORTI TAL-APPELL

IMĦALLFIN

S.T.O. PRIM IMĦALLEF MARK CHETCUTI
ONOR. IMĦALLEF GIANNINO CARUANA DEMAJO
ONOR. IMĦALLEF ANTHONY ELLUL

Seduta ta' nhar it-Tnejn, 12 ta' Ġunju, 2023.

Numru 3

Appell numru 615/2022/1

***JV Healthcare Limited* (C-42953)**

v.

1. *Cherubino Limited* (C-3677);
2. Dipartiment tal-Kuntratti;
3. *Central Procurement and Supplies Unit*

1. Dan huwa appell ta' *JV Healthcare Limited* ["*JV*" jew "l-appellanti"] minn deċiżjoni tas-7 ta' Diċembru 2022 tal-Bord ta' Reviżjoni dwar Kuntratti Pubbliċi ["il-Bord ta' Reviżjoni"], imwaqqaf taħt ir-Regolamenti tal-2016 dwar l-Akkwist Pubbiku ["L.S. 601.03"], li laqa' oġġezzjoni mressqa minn *Cherubino Limited* ["*Cherubino*"] kontra l-għażla ta' *JV* bħala "offerent rakkomandat" għall-għoti ta' kuntratt pubbliku wara sejħa għal offerti mis-*Central Supplies and Procurement Unit* tal-Ministeru tas-Saħħa ["*CPSU*" jew "l-awtorità kontraenti"].

2. Is-*CPSU* għamlet sejħa għal offerti għall-provvista ta' prodott mediku. Fost il-kondizzjonijiet tas-sejħa kien hemm dik illi kull oblatur kellu, fid-dokument tal-offerta, jistqarr illi:

> »3.8 I confirm that the company I am representing is licensed by the competent authority in Europe to trade this medicinal product.«

3. Hemm ukoll kondizzjoni taħt "*section 2 - special conditions*" illi tgħid hekk:

> »9.11 Registration of medicinal products
>
> »… … …
>
> »For a centrally authorised medicinal product, a copy of the delegated responsibility as issued by the Marketing Authorisation Holder (MAH) is to be submitted with the first consignment.
>
> »… … …
>
> »For medicinal products registered by the contractor following the signing of the contract, a copy of the registration certificate issued by the Licensing Authority of Malta must be submitted to CPSU within 90 days from signing of the contract. If the product is not registered within the stipulated timeframe, the Contracting Authority will reserve the right to purchase the product on the account of the defaulting contractor until such time that the product is registered.«

4. Hemm ukoll kondizzjoni taħt "*section 3 - specifications*" illi tgħid hekk:

> »1.2.1 Medicinal products and food supplements
>
> »i) … … …
>
> »ii) If the medicinal product being offered is not registered locally, it is hereby confirmed that product/s shall be registered within 90 days from award of contract. Failure of this, the Contracting Authority reserves the right, at its own discretion, to purchase registered product on the account of the defaulting contractor until the product is locally registered.
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> »The Contracting Authority reserves the right to still consider other offers that are not locally or centrally registered to ensure availability of such medication.
>
> »For medicinal products that are not locally or centrally registered, the Contracting Authority reserves the right to request the responsible person (RP) of the economic operator to complete and submit an unlicensed form. In the absence of the economic operator's compliance to the above, offer may be rejected.«

5. Imbagħad, dwar l-awtorità li magħha jiġi reġistrat il-prodott, f'*section 4 – supplementary documentation* jingħad hekk:

> »4.2 – Glossary
>
> »… … …
>
> »Marketing Authorization (MA): is the licence for medicinal products to be placed on the market in Malta granted by the Medicines Authority in accordance with the Medicines Act, 2003 (Act No III of 2003 and subsidiary legislation) and for Centrally Authorized products, by the European Medicines Agency (EMA). Currently the three main types of procedures recognized for the granting of a marketing authorization and to place a product on the market in Malta are the National Procedures, European Procedures (Mutual Recognition and Decentralized Procedures), and Centralized Procedure.«

6. Il-prodott li dwaru saret is-sejħa huwa reġistrat mal-*European Medicines Agency* u għaldaqstant jitqies *centrally authorised*.

7. Fost dawk li tefgħu offerti kien hemm *JV* u *Cherubino*. B'ittra tal-24 ta' Ottubru 2022 l-awtorità kontraenti għarrfet lil *Cherubino* illi l-offerta tagħha twarrbet għax "*a cheaper and technical*[*ly*] compliant offer was recommended," u illi r-rakkomandazzjoni kienet illi l-kuntratt jingħata lil *JV.*

8. B'ittra tal-1 ta' Novembru 2022 *Cherubino* ressqet oġġezzjoni kontra din id-deċiżjoni quddiem il-Bord ta' Reviżjoni, u l-bord, bid-deċiżjoni tas-7 ta' Diċembru 2022 li minnha sar dan l-appell, iddeċieda hekk:

> »The board … … … concludes and decides:
>
> »a) to uphold the appellant's concerns and grievances;
>
> »b) to cancel the notice of award letter dated 24th October 2022;
>
> »c) to cancel the letter of rejection dated 24th October 2022 sent to *Cherubino Ltd*;
>
> »d) to order the contracting authority to re-evaluate all the bids received in the tender through a newly constituted evaluation committee composed of members which [*sic*] were not involved in the original evaluation committee whilst also taking into consideration this board's findings;

»e) after taking all due consideration of the circumstances and outcome of this letter of objection, directs that the deposit be refunded to the appellant.«

9. Ir-raġunijiet li wasslu lill-Bord ta' Reviżjoni għal din id-deċiżjoni ġew imfissra hekk:

»The board … having noted the objection filed by *Cherubino Limited* (hereinafter referred to as the appellant) on 3rd November 2022[1] … whereby the appellant contends that:

»a) Preliminary – Reference is made to a request made to the Department of Contracts and the Central Procurement and Supplies Unit, wherein information about the brand, model and market authorization about the product submitted by *JV Healthcare Limited* was requested. In view of the fact that this information has not been supplied by the DoC[2]/CPSU, and this in manifest breach of article 40 of the PPR[3], Cherubino is respectfully requesting the board to order DoC/CPSU to issue the requested information and to re-issue the rejection letter and this to ensure that the legal principle of equality of arms is upheld.

»b) Messrs. *JV Healthcare Limited* does not meet the tender requirements – Although no confirmation was forthcoming from the DoC/CPSU, it is safe to say that the recommended bidder's offer is in breach of the tender specifications, most notably provision 3.8 of the tender offer form. The product being offered is not registered and/or has not been registered and licensed by Messrs. *JV Healthcare Limited* and/or does not have the necessary authorization by the competent authorities to trade the medicinal product on offer.

»c) Doctrine of self-limitation – The doctrine of self-limitation is an important public procurement principle which has been referred to by this board on various occasions, which seeks to ensure that tenderers are adjudged only on the basis of conditions stipulated within the tender document, this will ensure predictability and transparency. The appellant company feels aggrieved by the decision of the evaluation committee, in particular since it failed to adhere to the mandatory requirement of the tender document, and in the process breaching this fundamental principle.

»This board also noted the contracting authority's reasoned letter of reply filed on 14th November 2022 and its verbal submission during the virtual hearing held on 1st December 2022, in that:

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1 L-ittra ġġib id-data tal-1 ta' Novenbru 2022 iżda waslet quddiem il-Bord ta' Reviżjoni fit-3 ta' Novembru 2022.

2 *Department of Contracts*

3 *Public Procurement Regulations* [L.S. 601.03]

»a) On the preliminary grievance – The grievance of the objector is that the information requested was not provided and is requesting for the cancellation and re issue of the letter of award. On this preliminary plea CPSU submits that the same information on the product name was forwarded to the objector on the basis of the Department of Contract policy that the brand and model of recommended products shall be disclosed if a request is made. In light of the above, the preliminary plea was unnecessary and should therefore be rejected unless withdrawn voluntarily by the objector. Moreover, CPSU submits that in such a situation a request for information shall made immediately after a recommendation is made. In the present case the request was made on the 31st of October 17.57, after office hours, whilst the objection was filed on the 3rd of November morning and received by CPSU at 11:41. In addition, the Department of Contract and/or CPSU never published the make/model/brand of the recommended bidder in the rejection letters but provide the same information upon request by any of the participating bidders. This case should not be an exception and there is no valid reason at law for the re-publication of the rejection letter as the disclosure of the brand/make/model are not a requirement under the Public Procurement Regulations.

»b) On the second grievance – CPSU submits that the tender document is clear in stating that it is the contractor's duty to register the product and it is not a *sine qua non* condition that the product is registered at the time of tender submission. So much so, section 9.11 of the special conditions provides that "For medicinal products registered by the contractor following the signing of the contract, a copy of the registration certificate issued by the Licensing Authority of Malta must be submitted to CPSU within 90 days from signing of the contract. If the product is not registered within the stipulated timeframe, the contracting authority will reserve the right to purchase the product on the account of the defaulting contractor until such time that the product is registered". The above is also reflected in Section 3 article 1.2.1 (ii) of the tender dossier which provides that: "If the medicinal product being offered is not registered locally, it is hereby confirmed that product/s shall be registered within 90 days from award of contract. Failure of this, the contracting authority reserves the right, at its own discretion, to purchase registered product on the account of the defaulting contractor until the product is locally registered". CPSU therefore submits that the evaluation committee was in its right and within the prescribed terms and specifications to recommend for award an offer which is not registered in Malta being the cheapest compliant offer. The onus would then shift on the contractor to obtain some form of registration in Malta from the licensing authority.

»Should the contractor fail to obtain some form of authorisation /license (*sic*) in Malta, then the contracting authority will have the right to purchase on the account of the contractor as provided in Section 3 article 1.2.1 (ii) of the tender dossier, quoted above. Moreover and without prejudice to the above submitted, it is being submitted that the present call for tenders is for a named

patient basis product for one patient only. In relation to named patient basis products, a procedure for a maximum number of 10 patients exists whereby the wholesaler, prescriber, patient, dispensing pharmacist, pharmaceutical unit of the licensing authority and the licensing authority can sign an application by means of which the product is exempted from registration. This procedure is an additional procedure to the other procedures available for economic operators to make their product available on the market. CPSU therefore submits that the evaluation committee was within its right and in observance of the tender document and the general principles of public procurement in recommending *JV Healthcare Limited*'s offer for award.

»c) On the third grievance – Principle of self limitation – On this count CPSU submits that its evaluation committee has throughout the evaluation process adhered to each and every fundamental principle of public procurement, including the principle of self limitation. In light of the above submission that the product at evaluation stage need not be already authorised or put on the market, the principle of self limitation has been strictly followed by the evaluation committee when making its recommendation.

»This board also noted the preferred bidder's reasoned letter of reply filed on 15th November 2022 and its verbal submission during the virtual hearing held on 1st December 2022, in that:

»a) *JV Healthcare Ltd* agrees completely with the reply issued by the Central Procurement and Supplies Unit to the objection lodged by *Cherubino Limited* dated 11th November 2022. *JV Healthcare* re-iterates that it has abided by all tender requirements and that the product supplied to CPSU will be a licenced product designated for use in Malta.

»This board also noted the DoC's reasoned letter of reply filed on 11th November 2022 and its verbal submission during the virtual hearing held on 1st December 2022, in that:

»a) Preliminary plea – The DoC submits that the current procurement process is administered and determined by the contracting authority since the estimated procurement value is €127,455.44 in accordance with regulation 9(1)(*a*) of the Public Procurement Regulations, 2016. Therefore, the DoC hereby submits that the Public Contracts Review Board should forthwith dismiss the objection with regard to the DoC since it is not the legitimate and proper defendant to reply to the grievances of the objector.

»This board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties including the testimony of the witnesses duly summoned, will consider appellant's grievances as follows:

»a) Preliminary – The board notes that this plea has been extinguished in the course of the hearing. The 'missing' information has at that stage been provided through the initial testimony of Dr Ian Ellul. Moreover, this board agrees with the written representations of the contracting authority whereby the make/model/brand of the recommended bidder are never and need not be

published in the rejection letters but such information is provided upon request by any of the participating bidders.

»b) Merits –

»Initially this board will list down what it considers to be most relevant to these proceedings. These are:

»i. Paragraph 9.11 – Section 2 of the tender dossier where it is stated "For medicinal products registered by the contractor following the signing of the contract, a copy of the registration certificate issued by the Licensing Authority of Malta must be submitted to CPSU within 90 days from the signing of the contract. … … …";

»ii. Testimony under oath of Ms Amanda Camilleri when she stated "No" when being asked by the appellant's legal representative if a product which is registered through the European Medicines Agency ("EMA") requires further registration with the Malta Medicines Authority;

»iii. Testimony under oath of Ms Amanda Camilleri whereby in respect of 'parallel trading' she stated that a new economic operator, in order to distribute an EMA registered medicinal product, needs to register with EMA in order to be issued with a 'parallel distribution authorisation'. She also stated that the Malta Medicines Authority is not involved at all in this process. She continued by testifying that, without this EMA authorisation, this product cannot be distributed within Maltese territory;

»iv. Spec 3.8 of the technical offer form which reads as follow: "I confirm that the company I am representing is licensed by the competent authority in Europe to trade this medicinal product". The answer to this spec by the preferred bidder was "Yes".

»Conclusions

»i. It is evidently clear from the wording of paragraph 9.11 – Section 2 of the tender dossier that the "90 days" allowance, following signing of the contract, is only to be granted in cases where the products are to be eventually registered with the licensing authority of Malta, *i.e*. the Malta Medicines Authority.

»ii. It is also very much clear, from the testimony of Ms Amanda Camilleri, that there are different ways and means on how a medicinal product is allowed to be distributed in Malta.

»iii. Such product offered by the preferred bidder is already registered with EMA. Hence it has been ascertained, during the course of the hearing, that what was needed was a 'parallel distribution authorisation'. These authorisations are issued by EMA and not by the Malta Medicines Authority.

»iv. Therefore, this Board opines that:

»A. paragraph 9.11 – Section 2 and its 90 days allowance are irrelevant to these proceedings since it is only referring to the licensing authority of Malta;

»B. the response provided by the preferred bidder in Spec 3.8 of its technical offer form is erroneous since at the time of closing date of the call for tenders, the preferred bidder was not in possession of such a document.

»v. The technical offer form being a note 3[4] document, no rectifications are allowable.

»Hence, this board cannot but uphold the appellant's grievance on the merits of this appeal.«

10. *JV* appellat b'rikors tat-23 ta' Diċembru 2022 u talbet illi din il-qorti "tħassar … id-deċiżjoni appellata … u tirrimanda l-atti lura lill-istess Bord ta' Reviżjoni dwar il-Kuntratti Pubbliċi għat-trattazzjoni u għad-deċiżjoni skond il-liġi". Id-dipartiment wieġeb fil-5 ta' Jannar 2023; *Cherubino* wieġbet fit-12 ta' Jannar 2023; u l-awtorità kontraenti wkoll wieġbet fit-12 ta' Jannar 2023.

11. Id-Dipartiment tal-Kuntratti ["id-dipartiment"] ressaq eċċezzjoni preliminari li trid li d-dipartiment jinħeles mill-ħarsien tal-ġudizzju billi ma għandux leġitimazzjoni passiva taħt ir-reg. 285 tal-L.S. 601.03 biex ikun parti f'dan l-appell għax ma huwiex l-awtorità kontraenti.

12. Ir-reg. 285 igħid hekk:

»**285.** Ir-rikors tal-appell għandu jkun indirizzat kontra l-awtorità responsabbli għat-tmexxija tas-sejħa, l-awtorità kontraenti, l-offerent rakkomandat, jekk ikun hemm, u kull parti oħra involuta fil-proċeduri quddiem il-Bord ta' Reviżjoni dwar Kuntratti Pubbliċi … … …«

13. Id-dipartiment kien parti fil-proċeduri quddiem il-Bord ta' Reviżjoni u għamel ukoll sottomissjonijiet. Tassew illi fost dawk is-sottomissjonijiet kien hemm dik illi "*the D*[*epartment*] *o*[*f*] *C*[*ontracts*] *… is not the legitimate and proper defendant to reply to the grievances of the objector*".

[4] »Note 3. No rectification shall be allowed. Only clarifications on the submitted information may be requested.«

Għalkemm huwa minnu illi, fiċ-ċirkostanzi tal-każ tallum, id-dipartiment ma kellux ikun parti, billi l-awtorità kontraenti hija s-*CPSU*, madankollu l-bord ma ta ebda deċiżjoni dwar dik l-eċċezzjoni u ma ħelisx lid-dipartiment mill-ħarsien tal-ġudizzju. Għalhekk ladarba d-dipartiment baqa' "parti involuta" fil-proċeduri, għandu jkun ukoll parti f'dan l-appell, u l-eċċezzjoni hija miċħuda, bla ħsara naturalment għal dak li sejra tiddeċiedi l-qorti dwar l-ispejjeż billi d-dipartiment mill-bidunett kien imħarrek ħażin.

14. Ngħaddu issa għall-meritu tal-appell. L-ewwel aggravju ġie mfisser hekk:

> »I Perjodu ta' disgħin jum għar-reġistrazzjoni tal-prodott f'Malta
>
> »Paragrafu 9.11 tat-tieni sezzjoni tal-i*special conditions* tat-*tender de quo* jiddisponi testwalment:
>
> > »"For medicinal products registered by the contractor following the signing of the contract, a copy of the registration certificate issued by the Licensing Authority of Malta must be submitted to CPSU within 90 days from signing of the contract."
>
> »Aktar minn hekk, artikolu 1.2.1(ii) tat-tielet sezzjoni tat-*tender* in kwistjoni jiddisponi testwalment:
>
> > »"If the medicinal product being offered is not registered locally, it is hereby confirmed that product/s shall be registered within 90 days from award of contract."
>
> »Huwa evidenti, għalhekk, li ma kienx hemm il-ħtieġa li l-prodott ikun reġistrat għal użu ġewwa Malta fil-mument illi jintefgħu l-offerti f'dan il-każ, u dan għaliex l-offerenti kollha kellhom perjodu ta' disgħin (90) jum li matulu, jekk kemm-il darba jkunu ngħataw il-kuntratt *de quo,* huma jkunu jistgħu jottjenu tali reġistrazzjoni.
>
> »Kif ingħad fis-sentenza fl-ismijiet *Cherubino Limited v*. Dipartiment tal-Kuntratti *et*, mogħtija minn din il-Qorti tal-Appell (sede superjuri) nhar it-3 t'Ottubru 2017:
>
> > »"Fuq dan il-punt, din il-qorti tirrileva li l-kwistjoni ta' liċenzji u ta' kif se jiġi impurtat il-prodott offrut ġewwa Malta ma hijiex materja li għandha tinteressa lill-awtorità kontraenti jew lill-bord. Kif jiġi esegwit il-kuntratt meta jingħata mhux kwistjoni li jrid jidħol fiha l-bord. Din il-qorti trattat punt simili fil-kawża *Joe Micallef & Son Express Skip Services Ltd v*. Id-Direttur tal-Anzjani u Kura fil-Komunità u fis-sentenza tagħha tas-27 ta' Ġunju 2014 stabbiliet dan il-prinċipju. Ġie osservat hekk fir-rigward:
> >
> > > »"'*Inoltre*, il-liġi trid li min ikun involut fi trasport ta' merkanzija perikoluża jkollu mqar persuna waħda li jkun konsulent biċ-ċertifikat *DGSA*[5]. Dan ifisser li biex l-appellat Saviour Mifsud

[5] *Dangerous goods safety adviser*

> ikun konformi mal-liġi jrid jiżgura li jaħtar konsulent tas-sigurtà għat-trasport li jkollu dan iċ-ċertifikat. Mhux meħtieġ li dan Saviour Mifsud personalment ikollu dan iċ-ċertifikat, iżda li jaħtar konsulent b'din il-kwalifika. Din kwistjoni, però, li tolqot l-esekuzzjoni tal-kuntratt, u kif intqal mill-Qorti Suprema tal-Kanada fis-sentenza *Double N Earthmovers Ltd v.* Edmonton (City), deċiża fil-25 ta' Jannar, 2007 (każ 2007 SCC3), li kienet tikkonċerna wkoll ġarr ta' skart, "*to impose a duty on owners to investigate whether a bidder will comply with the terms of its bid would overwhelm and ultimately frustrate the tender process by creating unwelcome uncertainties … Whether or not the bidder is, at the time of tender, capable of performing as promised is irrelevant in the light of the bidder's legal obligation to do so once its bid is accepted*.'
>
> »"Mill-kumpless taċ-ċirkostanzi f'każ ta' sejħa li ma tinsistix mod ieħor, mhux mehtieg li offerent ikun, meta jitfa' l-offerta, f'posizzjoni li jwettaq dak li obbliga ruħu li jwettaq, basta li dak li jkun jimpenja ruħu li jwettaq is-servizz skont id-dettami tal-liġijiet viġenti tal-pajjiż. L-offerent rebbieħ huwa dejjern marbut li fil-qadi ta' dmirijietu josserva l-liġijiet kollha tal-pajjiż.
>
> »"Fid-dawl tal-premess, jirriżulta li kemm id-deċiżjoni tal-bord tal-25 ta' April 2017, kif ukoll id-deċiżjoni li ħareġ id-Dipartiment tal-Kuntratti b'ittra tas-17 ta' Marzu 2017 huma ħżena u qed jiġu mħassra, u s-soċjetà rikorrenti għandha titpoġġa fis-sitwazzjoni li kienet qabel il-ħruġ ta' dan ir-rifjut, biex l-offerta tagħha tiġi kkunsidrata mill-ġdid."
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> »Għalhekk il-bord kien skorrett meta, essenzjalment, iddeċieda li l-prodotti li jiġu offruti mill-offerenti jridu jkunu ġà ġew debitament reġistrati fil-mument li tkun saret l-offerta.
>
> »Jekk il-bord kien tal-fehma illi t-terminu ta' disgħin (90) jum kif stipulat f'paragrafu 9.11 fit-tieni sezzjoni kien irrilevanti għall-proċeduri odjerni, billi tali terminu kien jirreferi biss għall-awtorità Maltija, ossija għall-*Malta Medicines Authority,* allura l-istess bord messu għadda sabiex irrevoka l-proċess intier tat-*tender de quo,* billi dan kien jikkostitwixxi *a material breach* tal-kondizzjonijiet tat-*tender*.
>
> «Meta ma għamilx hekk, il-bord ġie li ffavorixxa lil *Cherubino*, li hija l-aġent lokali tal-manifattur, filwaqt illi offerenti oħrajn normalment jużaw il-perjodu msemmi ta' disgħin (90) jum sabiex jottjenu d-debita reġistrazzjoni jekk kemm-il darba huma jkunu ngħataw il-kuntratt in kwistjoni, u dan kif minn dejjem kienet l-intenzjoni tal-esponenti li tagħmel, u kif fil-fatt għamlet … … …
>
> »Għalhekk biss, l-esponenti hija tal-fehma illi d-deċiżjoni appellata timmerita li tiġi mħassra u revokata.«

15. Id-dipartiment u l-awtorità kontraenti jaqblu mal-appellanti illi d-deċiżjoni tal-Bord ta' Reviżjoni hija ħażina u għandha titħassar u tinqaleb.

16. *Cherubino* min-naħa l-oħra tgħid illi d-deċiżjoni appellata hija tajba; wieġbet hekk:

»Jidher li s-soċjetà *JV* in sostenn tal-ewwel aggravju tagħha tgħid li s-sejħa tagħti l-fakultà lill-oblaturi sabiex jirreġistraw il-prodott … disgħin (90) jum wara l-għoti tal-kuntratt, mal-awtoritajiet lokali.

»Sabiex tissostanzja dan, is-soċjetà *JV* tgħid u tispjega li, *ai termini* tas-sejħa, senjatament artikolu 1.2.1 tat-tielet sezzjoni, prodotti mediċinali li ma humiex reġistrati f'Malta għandhom perjodu ta' disgħin jum mill-ġurnata li l-offerta tiġi milqugħa.

»Tkompli s-soċjetà *JV* tgħid li "… ma kienx hemm il-ħtieġa li l-prodott ikun reġistrat għal użu ġewwa Malta fil-mument illi jintefgħu l-offerti …" u għalhekk, skont *JV*, "… il-bord kien skorret meta, essenzjalment, iddeċieda li l-prodotti li jiġu offruti mill-offerenti jridu jkunu ġà ġew debitament reġistrati fil-mument li tkun saret l-offerta".

»*JV* ma' fehmet xejn minn dak li kien mitlub mill-offerta u wisq anqas minn dak deċiż mill-bord.

»Il-punt tat-tluq għandu jkun dak iddikjart mill-oblatur fl-offerta tiegħu. *JV* fit-*technical offer form* tagħha ikkonfermat li hi għandha l-liċenzja u l-awtorizzazzjoni neċessarja sabiex tikkumerċjalizza l-prodott, u dana billi stqarret li "*I confirm that the company* I *am representing* is *licenced* by *the competent authority in Europe to trade this medicinal product*".

»Iżda tuI il-proċeduri (ukoll fir-rikors tal-appell) ġie stabilit mingħajr ebda dubju li:

»L-ewwel mhux minnu li *JV* għandha xi awtorizazzjoni mill-*European Medicines Authority* [*recte*, *European Medicines Agency*] sabiex tikkumerċjalizza l-prodott …;

»It-tieni ġie stabilit li effetivament ma saret l-ebda taIba għal awtorizzazzjoni ta' *parallel distribution authorisation* mal-*European Medicines Authority* sal-ġurnata li ġiet sotto-messa l-offerta ta' *JV*;

»It-tielet ma ġiet sottomessa l-ebda konferma li *JV* għandha r-rap-preżentanza (kif tgħid li għandha] ta' xi kumpannija estera, u/jew għandha li *letter of access* kif talvolta ikkonfermat li għandha *Cherubino*;

»Ir-raba' li għall-prodott in kwistjoni, ġaladarba dan huwa rreġistrat mal-*European Medicines Authority*, ma hemm l-ebda reġistrazzjoni possibli lokalment.

»B'dik li hija l-konsegwenza ċara u ovvja, li dak li stqarret f'artikolu 3.8 fit-*technical offer* form ta' *JV* ma' hi xejn għajr *misrepresentation* li ma tistax tiġi ssanata f'dan l-istadju, ġaladarba tifforma parti minn *note 3*.

»Dak li qed tippretendi s-soċjetà *JV* ma huwa xejn ħlief ksur tal-prinċipju ta' *self-limitation* – billi qed tippretendi li jinkisru l-kundizz-jonijiet tas-sejħa, sabiex tkun f'posizzjoni li tissana l-offerta tagħha.

»Hawn issir referenza għad-deċiżjoni tal-Qorti Ewropea fl-ismijiet <u>*Nexans France v. European Joint Undertaking for ITER and the Development of Fusion Energy*</u> [T-415/10]4, fejn intqal *inter alia* li,

> »"It must be borne in mind at the outset that where, in the context of a call for tenders, the contracting authority defines the conditions which it intends to impose on tenderers, it places a limit on the exercise of its discretion and, moreover, cannot depart from the conditions which it has thus defined in regard to any of

> the tenderers without being in breach of the principle of equal treatment of candidates. It is therefore by reference to the principles of self-limitation and respect for equal treatment of candidates that the Court must interpret the tender specifications'."

»Għalhekk kien korrett il-bord meta wasal għall-konklużjoni li.

> »"The response provided by the preferred bidder in Spec 3.8 of its technical offer form is erroneous since, at the time of closing date of the call for tenders, the preferred bidder was not in possession of such a document".«

17. Ir-raġunament li wassal lill-Bord ta' Reviżjoni biex jilqa' l-oġġezzjoni ta' *Cherubino* huwa dan: biex *JV* tista' tbigħ il-prodott f'Malta teħtieġ i. illi l-prodott ikun reġistrat mal-awtorità kompetenti u ii. illi *JV* jkollha awtorizzazzjoni illi tinnegozja fil-prodott, dik illi l-Bord ta' Reviżjoni sejħilha *parallel distribution authorisation*. *JV* tgħid illi, taħt il-klawsoli 9.11 u 1.2.1(ii) tal-kondizzjonijiet tas-sejħa[6], għandha disgħin jum minn dakinhar li tingħata l-kuntratt biex tipproduċi d-dokumenti relativi. Il-bord iżda kien tal-fehma illi dawn id-disgħin jum igħoddu biss meta l-prodott irid jiġi reġistrat mal-Awtorità dwar il-Mediċini ta' Malta mwaqqfa taħt l-art. 4 tal-Att dwar il-Mediċini ["Kap. 458"] u għalhekk għandhom relevanza biss għar-reġistrazzjoni tal-prodott f'Malta mal-awtorità Maltija u mhux ukoll għall-awtorizzazzjoni – il-*parallel distribution authorisation* – tal-operatur ekonomiku, billi din l-awtorizzazzjoni tingħata mill-awtorità Ewropea u mhux minn dik Maltija. Għalhekk, il-bord ikkonkluda illi *JV* kellha jkollha din l-awtorizzazzojni meta tefgħet l-offerta u mhux sa disgħin jum wara li tingħata l-kuntratt.

18. Mad-daqqa ta' għajn jidher illi l-Bord ta' Reviżjoni kellu raġun. Jekk *JV* ma kellhiex *parallel distribution authorisation* fil-waqt li għamlet l-offerta ma

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6 Para. 3, *supra*

setgħetx tiddikjara illi "*I confirm that the company I am representing is licensed by the competent authority in Europe to trade this medicinal product*".

19. Il-kwistjoni iżda hija jekk hijiex meħtieġa *parallel distribution authorisation* għal prodott li huwa *centrally authorised* għax reġistrat mal-*European Medicines Agency*. Dwar dan, ir-rappreżentant tal-Awtorità dwar il-Mediċini ta' Malta xehdet quddiem il-Bord ta' Reviżjoni:

> »… … … the product … is registered with the European Medicines Agency (EMA) and is authorised for use in every member state with local distribution registration in Malta. Economic operators can apply for parallel trading permits but without such permits the product cannot be marketed in Malta.«

20. Xehed ukoll ir-rappreżentant ta' *Cherubino* u qal hekk:

> »Dr Francis Cherubino … testified on oath that he is a director of *Cherubino Ltd* … and that his company is authorised to market the product in Malta as it is registered and has a letter of access from the manufacturer. Witness explained that one needs the permit of the company through a letter of access to distribute the product and thereafter there is no need for further registration. If one is not the official distributor then one needs to apply to EMA to furnish parallel distribution notice. Cherubino has such letter of access confirming that it is licensed in Europe to distribute this product in terms of article 3.8 of the tender. There are no records displayed in the public register of EMA that any one has a permit for parallel distribution. *Cherubino*'s bid meets the requirement of article 3.8 but no one else does.«

21. Jekk dak li qiegħed igħid ir-rappreżentant ta' *Cherubino – viz*. illi "*one needs the permit of the company through a letter of access to distribute the product*" – huwa minnu, mela *Cherubino* għandha s-setgħa li ma tħalli li ħadd ieħor jitfa' offerta. Dan huwa manifestament żbaljat u jmur kontra kull prinċipju ta' konkorrenza fis-suq billi jeskludi l-*parallel importation/distribution*.

22. Iżda hija meħtieġa *parallel distribution authorisation* – ukoll jekk mhux mingħand *Cherubino* stess – biex operatur ekonomiku jinnegozja fi prodott reġistrat mal-*European Medicines Agency*?

23. Il-materja hija regolata bir-Regolament (KE) nru 726/2004 tal-Parlament Ewropew u tal-Kunsill tal-31 ta' Marzu 2004 li jistabbilixxi proċeduri Komunitarji għall-awtorizzazzjoni u s-sorveljanza ta' prodotti mediċinali għall-użu mill-bniedem u veterinarju u li jistabbilixxi l-Aġenzija Ewropea għall-Mediċini ["Reg. 726/2004"] u bid-Direttiva 2001/83/KEE tal-Parlament Ewropew u tal-Kunsill tas-6 ta' Novembru 2001 dwar il-kodiċi tal-Komunità li għandu x'jaqsam ma' prodotti mediċinali għall-użu mill-bniedem ["Dir. 2001/83"].

24. L-art. 57(1)(*o*) tar-Reg. 726/2004 igħid hekk:

> »Artikolu 57
>
> »1. L-Aġenzija għandha tipprovdi lill-Istati Membri u lill-istituzzjonijiet tal-Komunità bl-aħjar pariri xjentifiċi possibbli dwar kull kwistjoni relatata mal-valutazzjoni tal-kwalità, sigurtà u effikaċja tal-prodotti mediċinali għall-użu mill-bniedem jew veterinarju li tkun irreferita lilha skond id-disposizzjonijiet tal-leġislazzjoni tal-Komunità dwar il-prodotti mediċinali.
>
> »Għal dan il-għan, l-Aġenzija … għandha twettaq ix-xogħol li ġej:
>
> » … … …
>
> »(*o*) tivverifika li l-kondizzjonijiet stabbiliti fil-leġislazzjoni tal-Komunità dwar prodotti mediċinali u fl-awtorizzazzjonijiet għall-*marketing* huma osservati fil-każ tad-distribuzzjoni parallela tal-prodotti mediċinali awtorizzati skond dan ir-Regolament.«

25. L-art. 76 tad-Dir. 2001/83 igħid hekk:

> »Artikolu 76
>
> »… … …
>
> »3. Kull distributur li ma jkunx detentur ta' awtorizzazzjoni għal tqegħid fis-suq li jimporta prodott mediċinali minn Stat Membru ieħor għandu jinnotifika dwar l-intenzjoni tiegħu li jimporta l-prodott mediċinali, lid-detentur ta' awtorizzazzjoni għal tqegħid fis-suq u lill-

> awtorità kompetenti fl-Istat Membri fejn ikun se jimporta dak il-prodott.
> … … …
>
> »4. Fil-każ ta' prodotti mediċinali li jkunu ngħataw awtorizzazzjoni skont ir-Regolament (KE) Nru 726/2004, id-distributur għandu jissottometti n-notifikazzjoni skont il-paragrafu 3 ta' dan l-Artikolu lid-detentur tal-awtorizzazzjoni għal tqegħid fis-suq u lill-Aġenzija. Miżata għandha tkun pagabbli lill-Aġenzija talli tiċċekkja li l-kundizzjonijiet stipulati fil-leġiżlazzjoni tal-Unjoni dwar il-prodotti mediċinali jkunu osservati.«

26. Dawn id-disposizzjoniiet tal-liġi juru illi dak li hu meħtieġ ma huwiex *parallel distribution authorisation* iżda biss "notifikazzjoni"; l-awtorizzazzjoni hija meħtieġa għall-prodott – li huwa ġà reġistrat u għalhekk awtorizzat – u mhux għad-distribuzzjoni tiegħu. Li jkun meħteġ imbagħad huwa illi l-*parallel distribution notice* – u mhux "*the delegated responsibility as issued by the Marketing Authorisation Holder*" kif erronjament tissejjaħ fil-klawsola 9.11[7] – tiġi "*submitted with the first consignment*", u mhux flimkien mal-offerta, kif fehem il-Bord ta' Reviżjoni.

27. Effettivament dan ifisser illi d-dikjarazzoni li jrid id-dokument tas-sejħa illi "*I confirm that the company I am representing is licensed by the competent authority in Europe to trade this medicinal product*" hija superfluwa fiċ-ċirkostanzi tal-każ tallum. Ifisser ukoll illi l-premessa illi "*The response provided by the preferred bidder in Spec 3.8 of its technical offer form is erroneous*", illi fuqha hija msejsa d-deċiżjoni tal-Bord ta' Reviżjoni, hija ħażina; konsegwentement, id-deċiżjoni wkoll hija ħażina.

28. Il-qorti għalhekk tilqa' dan l-ewwel aggravju tal-appellanti u, billi dan hu biżżejjed biex jintlaqa' l-appell, ma jibqax meħtieġ li nqisu l-aggravji l-oħra.

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7 Para. 3, *supra*

29. Il-qorti għalhekk tilqa' l-appell tħassar id-deċiżjoni appellata u, kif mitluba fir-rikors tal-appell, tibgħat l-atti lura lill-Bord ta' Reviżjoni. L-ispejjeż ta' dan l-appell jitħallsu minn *Cherubino*.

Mark Chetcuti Prim Imħallef	Giannino Caruana Demajo Imħallef	Anthony Ellul Imħallef

Deputat Reġistratur
da